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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,714	03/16/2004	Takahiko Ono	40072-0006	1024
26633	7590	04/03/2006	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP			TOWA, RENE T	
1717 RHODE ISLAND AVE, NW			ART UNIT	
WASHINGTON, DC 20036-3001			PAPER NUMBER	

3736

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/800,714	<b>Applicant(s)</b> ONO ET AL.	
	<b>Examiner</b> Rene Towa	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/27/05, 3/16/04</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In regards to claims 7-12, the omitted step is: a step for diagnosing the sleep apnea syndrome as disclosed in the preamble.

In regards to claim 15, the omitted step is: a step for analyzing the signal as disclosed in the preamble.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sullivan (US Patent No. 5,989,193).

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In regards to claim 1, Sullivan disclose(s) a sleep apnea syndrome diagnosing device 10, comprising:

a snoring sound collector 11 which collects snoring sound;

a snoring sound holder 19 which holds the collected snoring sound;

a correlation coefficient calculator 16 which is capable of dividing a time axis of the snoring sound held in the snoring sound holder 19 into plural cycles and which is capable of sequentially calculating a correlation coefficient between the snoring sound of one cycle and the snoring sound of a cycle next to the one cycle; and

an output section 19 which outputs the correlation coefficient calculated by the correlation coefficient calculator 16 (see figs. 1 & 4; column 3/line 57-column 4/line 6; column 4/lines 32-44; column 6/lines 40-43).

In regards to claim 2, Sullivan disclose(s) a sleep apnea syndrome diagnosing device 10 wherein the correlation coefficient calculator 16 comprises:

a reference data moving period setter which is capable of setting a reference data moving period having a first length longer than a length of the cycle on the time axis of the snoring sound;

a comparison data moving period setter which is capable of setting a comparison data moving period having a second length longer than the length of the cycle on the time axis of the snoring sound, the comparison data moving period being shifted from the reference data moving period by a first predetermined period;

a combination calculator 16 which is capable of calculating correlation coefficients respectively on combinations of cycles set by shifting within the reference

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data moving period by a second predetermined period each time and cycles set by shifting within the comparison data moving period by a third predetermined period each time; and

a representative value extractor 16 which is capable of extracting a representative value based on the correlation coefficients calculated by the combination calculator 16 (see figs. 1 & 4; column 6/lines 40-43).

In regards to claim 3, Sullivan disclose(s) a sleep apnea syndrome diagnosing device 10 wherein the combination calculator 16 is capable of calculating correlation coefficients on all the combinations of the cycles set by shifting within the reference data moving period by the second predetermined period each time and the cycles set by shifting within the comparison data moving period by the third predetermined period each time (see figs. 1 & 4; column 6/lines 40-43).

In regards to claim 4, Sullivan disclose(s) a sleep apnea syndrome diagnosing device 10 wherein the representative value extractor 16 is capable of extracting a maximum value from values of the correlation coefficients calculated by the combination calculator 16 as the representative value (see figs. 1 & 4; column 6/lines 40-43).

In regards to claim 5, Sullivan disclose(s) a sleep apnea syndrome diagnosing device 10 wherein the second predetermined period and the third predetermined period are capable of coinciding with a data sampling period of the snoring sound held in the snoring sound holder 19 (see figs. 1 & 4; column 6/lines 40-43).

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In regards to claim 6, Sullivan disclose(s) a sleep apnea syndrome diagnosing device 10 wherein the output section is capable of outputting the correlation coefficients are capable of being calculated by the combination calculator 16 as a graph (see fig. 4).

In regards to claim 13, Sullivan disclose(s) a computer program product 10 including a medium capable of recording a program for diagnosing sleep apnea syndrome, the program being operable to execute the steps of:

collecting snoring sound and storing the collected snoring sound in a snoring sound holder 19 (i.e. via snoring sound collector 11 and a snoring sound holder 19);

dividing a time axis of the snoring sound held in the snoring sound holder 19 into plural cycles (i.e. via a correlation coefficient calculator 16);

sequentially calculating a correlation coefficient between the snoring sound of one cycle and the snoring sound of a cycle next to the one cycle; and

outputting the calculated correlation coefficient (i.e. via an output section 19) (see figs. 1 & 4; column 3/line 57-column 4/line 6; column 4/lines 32-44; column 6/lines 40-43).

In regards to claim 14, Sullivan discloses a signal analyzer 10, comprising:

a signal data holder 19 which is capable of holding signal data with irregular periodicity;

a correlation coefficient calculator 16 which is capable of dividing a time axis of the signal data held in the signal data holder 19 into plural cycles and sequentially calculating a correlation coefficient between the signal data of one cycle and the signal data of a cycle next to the one cycle; and

an output section 19 which is capable of outputting the correlation coefficient calculated by the correlation coefficient calculator 16 (see figs. 1 & 4; column 3/line 57- column 4/line 6; column 4/lines 32-44; column 6/lines 40-43).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan ('193) in view of Rapoport et al. (US Patent No. 5,490,502).

In regards to claims 7 and 15, Sullivan disclose(s) a sleep apnea syndrome diagnosing method, comprising the steps of:

collecting snoring sound and storing the collected snoring sound in a snoring sound holder 19;

dividing a time axis of the snoring sound held in the snoring sound holder 19 into plural cycles (see fig. 4).

In regards to claim 12, Rapoport et al. disclose(s) a sleep apnea syndrome diagnosing method wherein in the step of outputting the result is outputted as a graph (see fig. 4).

***Sullivan does not disclose calculating a sequentially calculating a correlation coefficient of the snoring sound. However, Rapoport et al. disclose a sleep apnea syndrome diagnosing method wherein a correlation coefficient of a***

***signal (52, 54) is sequentially calculated and displayed (see fig. 13; column 8/lines 49-67).***

In regards to claim 8, Rapoport et al. disclose(s) a sleep apnea syndrome diagnosing method wherein the step of calculating the correlation coefficient comprises the steps of:

setting a reference data moving period 50 having a first length longer than a length of the cycle on the time axis of the signal;

setting a comparison data moving period (52, 54) having a second length longer than the length of the cycle on the time axis of the signal, the comparison data moving period being shifted from the reference data moving period by a first predetermined period;

calculating correlation coefficients on respective combinations of cycles set by shifting within the reference data moving period by a second predetermined period each time and cycles set by shifting within the comparison data moving period by a third predetermined period each time; and

extracting a representative value based on the calculated correlation coefficients (see fig. 13; column 8/lines 49-67).

***It is noted that the method of Rapoport et al. discloses calculating a correlation coefficient over the entire waveform (i.e. a plurality of cycles) and outputting a single correlation coefficient (i.e. a representative correlation coefficient).***



In regards to claim 9, Rapoport et al. disclose(s) a sleep apnea syndrome diagnosing method wherein in the step of calculating the correlation coefficients on the respective combinations, the correlation coefficients are calculated on all the combinations of the cycles set by shifting within the reference data moving period 50 by the second predetermined period each time and the cycles set by shifting within the comparison data moving period (52, 54) by the third predetermined period each time (see fig. 13; column 8/lines 49-67).

In regards to claim 10, Rapoport et al. disclose(s) a sleep apnea syndrome diagnosing method wherein in the step of extracting the representative value, a maximum value is extracted from values of the calculated correlation coefficients as the representative value (see fig. 13; column 8/lines 49-67).

In regards to claim 11, Rapoport et al. disclose(s) a sleep apnea syndrome diagnosing method wherein the second predetermined period and the third predetermined period coincide with a data sampling period of the signal (see fig. 13; column 8/lines 49-67).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Sullivan with correlation coefficient calculating steps similar to those of Rapoport et al. in order to determine the degree of resemblance of an actual data set with a normal signal so as to establish whether or not there is a departure from normal.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,450,957 to Yoshimi et al. discloses a respiratory disease monitoring system.

US Patent No. 6,280,392 to Yoshimi et al. discloses an infant condition monitoring system and method using load cell sensor sheet.

US Patent No. 6,142,950 to Allen et al. discloses a non-tethered apnea screening device.

US Patent No. 6,283,119 to Bourdon discloses a breathing aid apparatus particular for treating sleep apnea.

US Patent No. 4,365,636 to Barker discloses a method of monitoring patient respiration and predicting apnea therefrom.

US Patent No. 6,306,088 to Krausman et al. discloses an ambulatory distributed recorders system for diagnosing medical disorders.

US Patent No. 4,617,525 to Lloyd discloses a sleep posture monitor and alarm system.

US Patent No. 5,914,660 discloses a position monitor and alarm apparatus for reducing the possibility of sudden infant death syndrome.

US Patent No. 3,911,899 to Hattes discloses a respiration monitoring method and apparatus.

US Patent No. 5,964,720 to Pelz discloses a method and system for monitoring the physiological condition of a patient.

US Patent No. 5,549,113 discloses an apparatus and method for remote monitoring of physiological parameters.


US Patent No. 6,045,514 to Raviv et al. discloses a method of measuring breathing resistance of a sleeping subject.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

  
**MAX F. HINDENBURG**  
**SUPPLEMENTARY PATENT EXAMINER**  
**ELECTRONIC BUSINESS CENTER 3700**